

## **REMARKS**

Claims 4-6 have been amended to replace the term “preventing” with the term “decreasing”. Support is found in the specification for example on page 12, which teaches that HGF provides a protective effect from developing retinopathy. New claims 7-12 have been added which are supported by the paragraph bridging pages 7-8 of the specification.

Claims 4-6 are rejected under 35 USC 112, first paragraph, for the reasons set forth.

The foregoing amendments address the “preventing” issue.

With regard to the remaining rejection under section 112, the HGF used in the present invention is explained in paragraphs [0017] through [0021]. In particular, these descriptions are fully sufficient for one of ordinary skill in the art to carry out the presently claimed invention, because any HGFs that have substantially the same activity as that of natural HGF can be used in accordance with the present invention. Further, methods for administration are explained in paragraphs [0022] through [0027], and therefore, one of ordinary skill in the art would not understand that a method for administration is only limited to intravenous injection.

In view of the foregoing, it is respectfully submitted that one skilled in the art would be fully enabled by the specification to practice the claimed invention without undue experimentation.

Claims 4-6 are further rejected under 35 USC 102 as anticipated by Machida et al., and claims 5-6 are rejected under 35 USC 102 as anticipated by Shibuki et al. These grounds of rejection are respectfully traversed.

With regard to the anticipation rejection by Machida et al., a verified English translation of the JP priority application No. 2004-23201 is submitted to remove Machida et al. as prior art.

With regard to Shibuki et al., the presently claimed invention is directed to the use of HGF for prevention or treatment of retinopathy, especially that resulting from damage and/or degeneration of the outer retinal layers (claim 4) and for prevention and treatment of macular degeneration or retinitis pigmentosa.

On the other hand, Shibuki et al. relate to the investigation of effect of HGF on a retinal ischemia/reperfusion model which is one of the models of retinopathy (lines 1-3 in the right column on page 528). The model disclosed in Shibuki et al. is used as a model of damage of the inner retinal layers, which is different from the damage and/or degeneration of the outer retinal layers as the target of the presently claimed invention.

Further, one of ordinary skill in the art would not have reasonably expected the preventive or therapeutic effect of HGF on the damage and/or degeneration of the outer retinal layers, only in view of the results obtained by the Shibuki et al. experiments by using the inner retinal layers.

The preventive or therapeutic effect of HGF on the damage and/or degeneration of the outer retinal layers is not obvious from the experimental results disclosed in the cited reference.

Retinitis pigmentosa is mentioned in the cited reference as one of the mere possibilities of target diseases to be prevented or treated with HGF as well as other numbers of disclosed retinal diseases. One of ordinary skill in the art would not have been able to understand or reasonably expect that HGF is indeed effective on a specific disease among the disclosed diseases without any experimental proof for treating the specific disease.

In view of the foregoing, it is respectfully submitted that each ground of rejection set forth in the Official Action has been overcome, and that the application is now in condition for allowance. Accordingly, such allowance is solicited.

Respectfully submitted,

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